IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Applicant:	Rebecca GOTTLIEB, et al.
Title:	SYSTEM AND METHOD FOR RESTENOSIS MITIGATION
Appl. No.:	10/638,215
Filing Date:	8/7/2003
Examiner:	Phillip A. Gray
Art Unit:	3767
Confirmation No.:	3315

APPEAL BRIEF UNDER 37 C.F.R. § 41.37

Mail Stop Appeal Brief – Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This communication is an Appeal Brief, responsive to the Final Office Action dated April 7, 2008, concerning the above-referenced patent application.

Under the provisions of 37 C.F.R. § 41.37, this Appeal Brief is being filed with the appropriate appeal fee under 37 C.F.R. 41.20(b)(2). If that fee is deemed to be insufficient, authorization is hereby given to charge any deficiency (or credit any balance) to the undersigned deposit account 19-0741.

I. Real Party In Interest

The real party in interest for the above referenced patent application and the present Appeal is the assignee of record for the above referenced patent application, Medtronic Minimed, Inc., as recorded at Reel 015267, Frame 0828.

II. Related Appeals And Interferences

Except for the matters noted in this section, Applicant is not aware of any related appeals, interferences or legal proceedings that would have a bearing on the Board's decision in the present Appeal.

Co-pending Divisional patent application no. 11/477,744 was filed on June 28, 2006, to include claims directed to subject matter that was withdrawn from the present application, following a restriction and election requirement. That Divisional patent application is presently pending and awaiting action by the U.S. Patent and Trademark Office.

III. Status Of The Claims

Claims 1-23 and 49-54 are pending in the application. Claim 1 is objected to and each of claims 1-23 and 49-54 is rejected under 35 U.S.C. 103(a), as discussed below.

Claims 24-48 had been cancelled without prejudice or disclaimer, after having been withdrawn from consideration as being directed to non-elected subject matter.

The present appeal relates to the objection to claim 1 and to each of the rejections of claims 1-23 and 49-54.

IV. Status Of Amendments

Applicant filed a response dated June 17, 2008, responsive to the Final Office Action of April 7, 2008. No further action from the U.S. Patent and Trademark Office was received by the date (September 5, 2008) of the filing of the Notice of Appeal or subsequent thereto.

V. Summary Of Claimed Subject Matter

Embodiments of the present invention relate, generally, to a method for mitigating restenosis at a site within a vasculature or at a trauma site at which a stent is located within a vasculature. The method of claim 1 involves positioning a catheter adjacent the trauma site. With reference to the example shown in Fig. 1, a catheter 12 is shown within a vein or artery 16, adjacent a trauma site.

The method of claim 1 further involves extending a sensor through a lumen in the catheter and through the stent to a position located outside of the catheter and outside of the stent. Again, with reference to the example shown in Fig. 1, a sensor 14 extends out from an end of the catheter 12 and extends through the stent 18 to a position outside of the catheter and the stent. In the embodiment of Fig. 1, the sensor 14 is extended to a position that is laterally offset and spaced to the left of the stent 18, such that the sensor 14 is not within the interior of the stent 18 (but, instead, is located outside of the stent 18).

The method of claim 1 further involves delivering a restenosis mitigating drug to the trauma site through the catheter. Again, with reference to the example embodiment of Fig. 1, the catheter 12 may have an outlet site for drug infusion at the end 12c. (See, e.g., paragraph [0025] of the present application.)

The method of claim 1 further recites that the sensor comprises an analyte sensor, physiological parameter sensor, biological parameter sensor, biochemical parameter sensor, or chemical parameter sensor. As discussed in the present specification (e.g., at paragraph [0030]), the sensing element 14 may sense an analyte, a physiological parameter, a biologicial parameter, a biochemical parameter, a chemical parameter or other parameter.

In a similar context, the method of claim 52 involves positioning a stent at the site and positioning a catheter adjacent the site. As noted above, the example embodiment in Fig. 1 shows a stent 18 at a site within a vasculature and a catheter 12 adjacent to that site.

Claim 52 also involves extending a sensor through the catheter and through the stent to a position located outside of the catheter and outside of the stent, while the stent is at the site and delivering infusion medium to the trauma site through the catheter. As noted above, the example embodiment in Fig. 1 shows a sensor 14 that is extended to a position that is laterally offset and spaced to the left of the stent 18, such that the sensor 14 is not within the interior of the stent 18 (but, instead, is located outside of the stent 18). In addition, the specification describes the catheter 12 as having an outlet site for drug infusion at the end 12c. (See, e.g., paragraph [0025] of the present application.)

The method of claim 52 further recites that the sensor comprises an analyte sensor, physiological parameter sensor, biological parameter sensor, biochemical parameter sensor, or chemical parameter sensor. As discussed in the present specification (e.g., at paragraph [0030]), the sensing element 14 may sense an analyte, a physiological parameter, a biologicial parameter, a biochemical parameter, a chemical parameter or other parameter.

Claims 1 and 52 are the only independent claims in the present Appeal. An example of a mapping of each of claims 1 and 52 to the specification is shown in the following charts.

Claim 1	Specification
A method for mitigating restenosis at a trauma site at which a stent is located within the vascular comprising:	Paragraphs [0006], [0007], [0022], Figs. 1 and 2, trauma site 15 and stent 18.
positioning a catheter adjacent the trauma site;	Paragraphs [0024] and [0033] and Figs. 1 and 2.
extending a sensor through a lumen in the catheter and through the stent to a position located outside of the catheter and outside of the stent; and	Paragraphs [0024], [0027] and [0028], Figs. 1 and 2, sensor 14.
delivering a restenoisis mitigating drug to the trauma site through the catheter	Paragraphs [0024], [0025], [0031], [0034] and [0035].
wherein the sensor comprises an analyte sensor, physiological parameter sensor, biological parameter sensor, biochemical parameter sensor, or chemical parameter sensor.	Paragraphs [0027], [0029], [0030] and [0038].

Claim 52	Specification
A method for mitigating restenosis at a site within a vasculature, the method comprising:	Paragraphs [0006], [0007], [0022], Figs. 1 and 2, trauma site 15 and vein or artery 16.
positioning a stent at the site;	Paragraphs [0007], [0023], [0033], Figs. 1 and 2, trauma site 15 and stent 18.
positioning a catheter adjacent the site;	Paragraphs [0007], [0023], [0033], Figs. 1 and 2, catheter 12.
extending a sensor through the catheter and through the stent to a position located outside of the catheter and outside of the stent, while the stent is at the site; and	Paragraphs [0024], [0027] and [0028], Figs. 1 and 2, sensor 14.
delivering infusion medium to the trauma site through the catheter;	Paragraphs [0024], [0025], [0031], [0034] and [0035].
wherein the sensor comprises an analyte sensor, physiological parameter sensor, biological parameter sensor, biochemical parameter sensor, or chemical parameter sensor.	Paragraphs [0027], [0029], [0030] and [0038].

VI. Grounds Of Objection And Rejection To Be Reviewed On Appeal

The Examiner objected to claim 1 "because of the following informalities: Examiner is unsure what applicant means by the terms – analyte sensor, physiological parameter sensor, biological parameter sensor, biochemical parameter sensor, or chemical sensor." In addition

the Examiner stated: "Examiner is unsure what constitutes various types of these sensors and what the definitions of these sensors are."

In addition, the Examiner rejected claims 1-23 and 49-54, as follows:

1. Claims 1-11, 14-23 and 49-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barry (U.S. Patent Application Publication No. 2002/0077592) in view of Adair et al. (U.S. Patent No. 6,211,904).

2. Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barry (U.S. Patent Application Publication No. 2002/0077592) in view of Adair et al. (U.S. Patent No. 6,211,904) and further in view of Silver (U.S. Patent No. 6,442,413).

3. Claims 4 and 19-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barry (U.S. Patent Application Publication No. 2002/0077592) in view of Adair et al. (U.S. Patent No. 6,211,904).

As noted in Section III, above, the present appeal relates to the above objection and each of the above rejections and, thus, all of the pending claims (i.e., claims 1-23 and 49-54).

VII. Argument

1. Appeal Of Objection To Claim 1

The Examiner objected to claim 1 "because of the following informalities: Examiner is unsure what applicant means by the terms – analyte sensor, physiological parameter sensor, biological parameter sensor, biochemical parameter sensor, or chemical sensor." In addition the Examiner stated: "Examiner is unsure what constitutes various types of these sensors and what the definitions of these sensors are."

The objection is respectfully traversed in that one of ordinary skill in the art would understand that an analyte sensor is a sensor that senses an analyte. Similarly, a physiological parameter sensor is a sensor that senses a physiological parameter. Also, a biological parameter sensor is a sensor that senses a biological parameter. A biochemical sensor is a sensor that senses a biochemical parameter. A chemical sensor is a sensor that senses a

chemical parameter. The present specification refers to these types of sensors, for example, in paragraphs [0027], [0029], [0030] and [0038].

It is respectfully submitted that one of ordinary skill in the art would understand the meaning of the term analyte as a substance or chemical constinuant that is determined in an analytical procedure. An analyte sensor would be understood by one of ordinary skill in the art to be a sensor that senses such a substance or chemical.

It is also respectfully submitted that one of ordinary skill in the art would understand the meaning of the phrase physiological parameter as a parameter of living organism. A physiological parameter sensor would be undertood by one of ordinary skill in the art to be a sensor that senses a parameter of a living organism.

It is also respectfully submitted that one of ordinary skill in the art would understand the meaning of the phrase biological parameter as a parameter of a biological entity. A biological parameter sensor would be undertood by one of ordinary skill in the art to be a sensor that senses a parameter of a biological entity.

It is also respectfully submitted that one of ordinary skill in the art would understand the meaning of biochemical and chemical. A biochemical parameter sensor would be undertood by one of ordinary skill in the art to be a sensor that senses a parameter of a biochemical. Similarly, a chemical parameter sensor would be understood by one of ordinary skill in the art to be a sensor that senses a parameter of a chemical.

It is respectfully submitted that the terms: analyte, physiological, biological, biochemical and chemical would have been well understood by those of ordinary skill in the art. Accordingly, the objection to claim 1 is respectfully traversed. In contrast, it is respectfully submitted that one of ordinary skill in the art would not consider a microendoscope (a viewing scope such as described by Adair et al.) to be a parameter sensor (much less an analyte sensor, physiological parameter sensor, biological parameter sensor, biochemical parameter sensor, chemical parameter sensor) or to function in any manner to sense such parameters. Instead, a microendoscope merely provides a surgeon with an image of whatever object is positioned in front of the lens of the scope, without regard to any parameter associated with the object. While images may be viewed through the

microendoscope, no parameters are sensed by a microendoscope. The microendoscope is oblivious to any parameters associated with any object in a captured image.

2. Appeal Of Rejection Of Claims 1-11, 14-23 and 49-54 Under 35 U.S.C. 103(a)

Claims 1-11, 14-23 and 49-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barry (U.S. Patent Application Publication No. 2002/0077592) in view of Adair et al. (U.S. Patent No. 6,211,904). In a separate section of the Office Action, the Examiner further rejected claims 4 and 19-23 under 35 U.S.C. 103(a) as being unpatentable over Barry (U.S. Patent Application Publication No. 2002/0077592) in view of Adair et al. (U.S. Patent No. 6,211,904). These rejections are addressed together herein, as the claims in the later-stated rejection are also included in the first-stated rejection and the rejections apply the same patent references.

As previously presented, claim 1 recites:

> A method for mitigating restenosis at a trauma site at which a stent is located within the vasculature comprising:
> positioning a catheter adjacent the trauma site;
> extending a sensor through a lumen in the catheter and through the stent to a position located outside of the catheter and outside of the stent; and
> delivering a restenosis mitigating drug to the trauma site through the catheter
> wherein the sensor comprises an analyte sensor, physiological parameter sensor, biological parameter sensor, biochemical parameter sensor, or chemical parameter sensor. (Emphasis added.)

As acknowledged by the Examiner on page 4 of the Office action, Barry does not disclose "extending a sensor . . . through the stent to a position located outside of the catheter and outside of the stent[.]" (Emphasis added.)

However, the Examiner states that "Adair et al. teaches that it is known to use the step of extending the sensor through the stent to a position located outside of the catheter and outside of the stent." (Office action, page 4.) The Examiner contends that it would have been obvious to modify Barry per the cited disclosures of Adair.

Applicants respectfully disagree with the above contention. Adair's microendoscope is not an analyte sensor, physiological parameter sensor, biological parameter sensor, biochemical parameter sensor, or chemical parameter sensor. Accordingly, while applicant respectfully traverses the Examiner's attempt to combine Adair with Barry to address the acknowledged deficiencies of Barry, such a combination would not result in the presently claimed invention. In particular, the Examiner's proposed combination would not result in extending an analyte sensor, physiological parameter sensor, biological parameter sensor, biochemical parameter sensor, or chemical parameter sensor through a lumen in the catheter and through the stent to a position located outside of the catheter and outside of the stent.

In addition, the proposed combination of Barry and Adair does not render claim 1 *prima facie* obvious because this combination would render the invention of Barry unsatisfactory for its intended purpose of regulating the heat treatment of an aneurysm. (See MPEP § 2143.01.) More specifically, Barry's temperature sensor 255 could not be located outside of the stent, without destroying the purpose and function of Barry's device.

Barry discloses that the heat treatment is provided by heating liquid 234 that is located inside of balloon 235. (See Paragraph [0088] and FIG. 14.) Heating the liquid induces thermal coagulation of aneurysmal wall 223. (See Paragraph [0089].) For accurately regulating the temperature of the liquid, a feedback control signal is required: this feedback control signal is provided by temperature sensor 255, which is positioned in the liquid. (See Paragraph [0089] and FIG. 14, which shows temperature sensor 255 as being located inside balloon 235.) Because stent 36 is also located inside balloon 235, the temperature sensor 255 is located inside both stent 35 and catheter 30.

Modifying Barry to require extending temperature sensor 255 through stent 36 to a position located outside of catheter 30 and outside of stent 36 would position the sensor outside of liquid 234. As such, the sensor would be rendered incapable of monitoring the temperature of liquid 234. Further, the sensor would be incapable of providing a feedback control signal for accurately regulating the heating of the liquid. Because modifying the position of the sensor, as proposed by the Examiner, would render the sensor incapable of monitoring the temperature of the liquid and providing an appropriate feedback control signal, it is believed that claim 1 is patentable over Barry in view of Adair.

Further, Applicants respectfully submit that Adair, alone, does not disclose all of the features recited in claim 1. For example, Adair does not disclose or suggest "delivering a restenosis mitigating drug to the trauma site through the catheter[.]" Adair discloses introducing a stent to force open a blockage of a blocked artery. (See Col. 19, lines 9-12.) Adair further discloses using a microendoscope to view the placement of the stent within the artery. (See Col. 19, lines 25-28.) However, Applicants are unable to find in Adair disclosure of "delivering a restenosis mitigating drug to the trauma site through the catheter[,]" as recited in claim 1.

In addition, as previously explained in Applicants' Amendment of December 18, 2007, Adair does not disclose or suggest "wherein the sensor comprises an analyte sensor, physiological parameter sensor, biological parameter sensor, biochemical parameter sensor, or chemical parameter sensor." In contrast, Adair discloses using image sensors, such as a microendoscope, in conjunction with a catheter. (See, for example, Col. 1, lines 19-25, and Col. 19, lines 8-9.) As explained in the previous paragraph, the microendoscope is for viewing a placement of a stent within an artery. A microendoscope can be used to view an image, but does not, itself, sense an analyte or a parameter. Because microendoscopes are distinguishable from an analyte sensor, physiological parameter sensor, biological parameter sensor, biochemical parameter sensor, or chemical parameter sensor, it is further believed that Adair, alone, does not disclose certain features of claim 1.

Therefore, it is believed that claim 1 is patentable over the cited art.

Claims 2-11, 14-23 and 49-51 depend, either directly or indirectly, from claim 1. At least for this reason, it is believed that claims 2-23 and 49-51 are patentable over the cited art.

As previously presented, claim 52 recites;

> A method for mitigating restenosis at a site within a vasculature, the method comprising:
>
> positioning a stent at the site;
>
> positioning a catheter adjacent the site;
>
> extending a sensor through the catheter and through the stent to a position located outside of the catheter and outside of the stent, while the stent is at the site; and

delivering infusion medium to the trauma site through the catheter;
wherein the sensor comprises an analyte sensor, physiological parameter sensor, biological parameter sensor, biochemical parameter sensor, or a chemical parameter sensor. (Emphasis added.)

At least for reasons similar to one or more reasons explained with respect to claim 1, it is believed that claim 52 is patentable over the cited art.

Claims 53 and 54 depend directly from claim 52. At least for this reason, it is believed that claims 53 and 54 are patentable over the cited art.

In the Section of the Final Office Action titled "Repsonse to Arguments," the Examiner stated that Applicant's argue that Barry and the rest of the prior art do not disclose "wherein the sensor comprises an analyte sensor, physiological parameter sensor, biological parameter sensor, biochemical parameter sensor, or chemical sensor," but that it is the Examiner's position that Barry's temperature sensor would be such a sensor. However, as discussed above, the pending claims recite extending the sensor through a lumen in the catheter and through the stent to a position located outside of the catheter and outside of the stent. In contrast, Barry's temperature sensor is located in the balloon area of the stent (and must be located in that area to function in the manner taught by Barry). To somehow position Barry's temperature sensor outside of the stent would effectively destroy the purpose and function of that temperature sensor.

Accordingly, Barry's temperature sensor does not meet the claimed invention, including extending an analyte sensor, physiological parameter sensor, biological parameter sensor, biochemical parameter sensor, or chemical parameter sensor through a lumen in the catheter and through the stent to a position located outside of the catheter and outside of the stent. Furthermore, while Adair shows a microendoscope located outside of a stent, Applicant has explained (above) that a microendoscope is not an analyte sensor, physiological parameter sensor, biological parameter sensor, biochemical parameter sensor, or chemical parameter sensor. Furthermore, Adair's placement of the microendoscope outside of a stent would not render it obvious to somehow modify Barry to move his temperature sensor outside of the stent because doing so would destroy the purpose and function of Barry's temperature sensor. Accordingly, the Examiner's responsive arguments

(alone or with the previously discussed expressed grounds of rejection) fail to raise a prima facie case of obviousness.

3. Appeal Of Rejection Of Claims 12 and 13 Under 35 U.S.C. 103(a)

Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barry (U.S. Patent Application Publication No. 2002/0077592) in view of Adair et al. (U.S. Patent No. 6,211,904) and further in view of Silver (U.S. Patent No. 6,442,413).

Claims 12 and 13 depend, either directly or indirectly, from claim 1. At least for this reason, it is believed that claims 12 and 13 are patentable over the Barry and Adair in the combination proposed by the Examiner. Furthermore, the Silver reference does not address the above-noted distinctions over Barry and Adair. Instead, the Examiner cited the Silver reference as allegedly describing the modification of delivery of a restenosis mitigating drug in response to the sensing of an analyte. However, like Barry and Adair, Silver fails to disclose or suggest extending an analyte sensor, physiological parameter sensor, biological parameter sensor, biochemical parameter sensor, or chemical parameter sensor through a lumen in the catheter and through the stent to a position located outside of the catheter and outside of the stent.

VIII. Conclusion

In view of the foregoing, it is respectfully submitted that claims 1-23 and 49-54 are in condition for allowance and the application should be allowed in its present form. In particular, it is respectfully submitted that the presently pending objection to claim 1 and rejections of claims 1-23 and 49-54 are improper and should be reversed for reasons as discussed above. In that regard, each of claims 1-23 and 49-54 is in condition for allowance.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or

even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date: November 5, 2008

By: _____

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VIII. Claims Appendix

1. (Previously Presented) A method for mitigating restenosis at a trauma site at which a stent is located within the vasculature comprising:

positioning a catheter adjacent the trauma site;

extending a sensor through a lumen in the catheter and through the stent to a position located outside of the catheter and outside of the stent; and

delivering a restenosis mitigating drug to the trauma site through the catheter

wherein the sensor comprises an analyte sensor, physiological parameter sensor, biological parameter sensor, biochemical parameter sensor, or chemical parameter sensor.

2. (Previously Presented) The method of Claim 1, further comprising locating the stent at the trauma site.

3. (Original) The method of Claim 2, wherein at least a portion of the catheter is positioned at an interior portion of the stent.

4. (Original) The method of Claim 1, wherein the restenosis mitigating drug is insulin.

5. (Original) The method of Claim 1, wherein the restenosis mitigating drug is delivered upstream from the trauma site.

6. (Original) The method of Claim 1, wherein the restenosis mitigating drug is dispersed to the trauma site through apertures in the catheter.

7. (Original) The method of Claim 1, wherein the catheter is a balloon catheter.

8. (Original) The method of Claim 7, further comprising disposing the restenosis mitigating drug on a balloon portion of the balloon catheter.

9. (Original) The method of Claim 8, wherein the balloon catheter abuts a wall of the vasculature at the trauma site after the balloon catheter is expanded.

10. (Original) The method of Claim 9, further comprising transferring the restenosis mitigating drug to the trauma site when the balloon catheter abuts the wall of the vasculature.

11. (Original) The method of Claim 9, wherein the restenosis mitigating drug is dispersed to the trauma site through apertures in the balloon catheter.

12. (Previously Presented) The method of Claim 1, further comprising sensing an analyte with the sensor.

13. (Original) The method of Claim 12, wherein the delivery of the restenosis mitigating drug is modified in response to the sensing of the analyte.

14. (Previously Presented) The method of Claim 12, wherein the analyte is glucose.

15. (Original) The method of Claim 1, further comprising adjusting a flow rate of the restenosis mitigating drug.

16. (Original) The method of Claim 6, further comprising adjusting a dispersal pattern of the restenosis mitigating drug.

17. (Original) The method of Claim 1, wherein the catheter is positioned prior to a stent procedure.

18. (Original) The method of Claim 1, wherein the catheter is positioned subsequent to a stent procedure.

19. (Original) The method of Claim 1, wherein the restenosis mitigating drug is nitric oxide.

20. (Original) The method of Claim 1, wherein the restenosis mitigating drug is an antibody.

21. (Original) The method of Claim 1, wherein the restenosis mitigating drug is a steroid.

22. (Original) The method of Claim 1, wherein the restenosis mitigating drug is an interleukin.

23. (Original) The method of Claim 1, wherein the restenosis mitigating drug is a blood thinner.

24.-48. (Cancelled)

49. (Previously Presented) The method of claim 1, wherein the sensor has a sensing element and wherein extending a sensor through a lumen in the catheter and through the stent comprises extending the sensor to position at which the sensing element is located on one side of and spaced from the stent.

50. (Previously Presented) The method of claim 1, wherein the sensor has a sensing element and wherein the catheter includes an outlet for delivering the restenosis mitigating drug and wherein delivering a restenosis mitigating drug comprises positioning the catheter relative to the stent so that the outlet is located on the opposite side of the stent relative to the side of the stent at which the sensing element is located.

51. (Previously Presented) The method of claim 1, wherein the sensor has a sensing element and wherein the catheter includes an outlet for delivering the restenosis mitigating drug and wherein delivering a restenosis mitigating drug comprises positioning the catheter relative to the stent so that the stent is located between the outlet and the sensing element.

52. (Previously Presented) A method for mitigating restenosis at a site within a vasculature, the method comprising:

positioning a stent at the site;

positioning a catheter adjacent the site;

extending a sensor through the catheter and through the stent to a position located outside of the catheter and outside of the stent, while the stent is at the site; and

delivering infusion medium to the trauma site through the catheter;

wherein the sensor comprises an analyte sensor, physiological parameter sensor, biological parameter sensor, biochemical parameter sensor, or a chemical parameter sensor.

53. (Previously Presented) A method of claim 52, wherein the sensor has a sensing element and wherein the catheter includes an outlet for delivering the infusion medium and wherein delivering infusion medium comprises positioning the catheter relative to the stent so that the stent is located between the outlet and the sensing element.

54. (Previously Presented) The method of claim 52, wherein the sensor has a sensing element and wherein extending a sensor through the catheter and through the stent comprises extending the sensor to position at which the sensing element is located on one side of and spaced from the stent.

IX. Evidence Appendix

None.

X. Related Proceedings Appendix

None.